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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,885	09/07/99	CURATOLO W	PC9824AJTJ

EXAMINER	
SHAREH, S	
ART UNIT	PAPER NUMBER
1616	5

HM12/0419

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DATE MAILED: 04/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/380,885	Curatolo et al
Examiner	**Group Art Unit**
Shahnam Sharareh	1616

☒ Responsive to communication(s) filed on *Sep 7, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-53* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-53* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for domestic priority under 35 U.S.C. 119(e)-(d).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 6, 10, 11, 14 rejected under 35 U.S.C. 102(b) as being anticipated by Ranade US Patent 4,803,076.

The instant claims are directed to a delayed release oral dosage form comprising a core containing sertraline and a pharmaceutically acceptable salt thereof coated with a polymer that is substantially impermeable to sertraline at the PH of the stomach.

Ranade disclose controlled release delivery systems comprising sertraline, and other desired excipients such as magnesium stearate or lactulose, and ethyl cellulose coated with methylene chloride solution of ethylene vinyl acetate copolymer and finally drying said tablets, wherein said tablets comprise multiple coats and dissolute in simulated intestinal fluid at a lower than 10% rate (see example 1 and 2 and 5, and figure 14 and 15.) Thus, Ranade meets the limitations set forth in the instant claims.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-53 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pfizer Inc WO 92/02212.

The instant claims are directed to a delayed release oral dosage form comprising a core containing sertraline and a pharmaceutically acceptable salt thereof coated with a polymer that is substantially impermeable to sertraline at the PH of the stomach, but permeable at the PH of the small intestine. The instant claims are also directed to method of treating patients in needs of sertraline therapy.

The international patent WO 92/02212 disclose the process of making a controlled release tablet or capsule comprising a core containing a therapeutic compound such as sertraline coated with a cellulose acetate or ethyl cellulose, and optionally a pore-forming material (see claims 1-2, 8, 10-13, 16, 20-25, examples 1-3.) Therefore, WO 92/02212 meet the limitations set forth in the

instant claims. In addition, the instant claims replete with recitations of functional limitations that further describe the action of the claimed core material following the dissolution of the instant polymeric coating. If the examiner finds that a prior art element performs the function specified in the claim, and is not excluded by any explicit definition provided in the specification for an equivalent, the examiner should infer from that finding that the prior art element is an equivalent, and should then conclude that the claimed limitation is anticipated by the prior art element (see MPEP 2183.) Accordingly, the cellulose acetate coating that is described in the cited prior art is a PH-sensitive coating that is degradable in an acidic environment. Even more, it is well known in the art that said coating is pharmaceutically equivalent to natural polymeric coatings such as hydroxymethylcellulose that are used in the instant invention, and therefore, inherently capable of being degraded at the presence of intestinal enzymes. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristics relied on. In re Swinehart , 439 F.2d 210, 212 - 13, 169 USPQ 226, 229 (C.C.P.A. 1971); and In re Fitzgerald , 619 F.2d 67, 205 USPQ 594 (CCPA 1980) (a case indicating that the burden of proof can be shifted to the applicant to show that the subject matter of the prior art does not possess the characteristic relied on whether the rejection is based on inherency under 35 U.S.C. 102 or obviousness under 35 U.S.C. 103) See MPEP 2183. Therefore, absence the showing of criticality of the claimed dissolution rate at various PH-

environment or enzyme-dependent condition, the instant claims are anticipated or in alternate obvious over the teachings of the international patent WO 92/02212.

Finally, although the international patent WO 92/0222 does not specifically teach the various therapeutic uses of their delayed release compositions, it teaches that such compositions may be used by patients requiring antianxiety therapy, thus methods of treating conditions in need of sertraline therapy would have also been obvious.

6. Claim 1-53 rejected under 35 U.S.C. 103(a) as being unpatentable over Bechgaard et al EP 0080341, in view of the teachings of Drug Facts and Comparisons.

The instant claims are directed to a delayed release oral dosage form comprising a core containing sertraline and a pharmaceutically acceptable salt thereof coated with a polymer that is substantially impermeable to sertraline at the PH of the stomach, but permeable at the PH of the small intestine. The instant claims are also directed to method of treating patients in needs of sertraline therapy.

Bechagaard et al disclose methods of preparing pharmaceutical oral controlled release multiple-unit compositions comprising a core containing an active therapeutic agent such as an antidepressant (see page 8 lines 20-24.) coated by a polymeric entity which is substantially resistant to gastric environment, but is erodible under the conditions in the small intestine. The coating of Bechagaard's may be selected from the group consisting of acrylic polymers and copolymers, cellulose acetate esters such as mixed particle esters of cellulose containing phthalate groups etc..and may further contain other suitable excipients such as surfactants, fillers, binders

and disintegrants (see claims 1,8-20.) Furthermore, the oral controlled release of Bechagaard are coated with a coating that is selectively eroded in the distal part of the small intestine, and will preferably release at least 90% of the active substance with in one hour at a PH of 7.5 (see page 14 lines 8-16.) Bechagaard et al, however, fail to specifically teach a sertraline containing enteric release dosage form.

It is well known in the art that oral pharmaceutical preparations that are associated with upper gastric irritation may be formulated in the form on an enteric coated tablet to minimize GI side effects that are associated with direct GI irritation of such drugs. Further, serotonin reuptake inhibitors such as sertraline have been shown to cause about 1% GI related side effects such as hemorrhagic peptic ulcer, stomatitis, and gastritis (see Facts and Comparison Page 1574 lines 16-20.) Therefore, one ordinary skilled in the art would have been motivated at the time of invention to formulate a enteric coated sertraline formulation, because he would have had a reasonable expectation to succeed in preparing oral dosage forms of sertraline that would produce less GI side effects and thus provide therapeutic benefits. One ordinary skilled artisan would have been motivated to further optimize the prior art conditions to achieve a desired rate of drug dissolution or a desired rate of disintegration of the enteric coating by routine experimentation. Furthermore, methods of treating psychiatric illness comprising administering to a patient in need of such delayed oral preparation would have also been obvious.

Conclusion

No claims were allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs 3/20/2000

JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616